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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,653	04/15/2004	David D. Barone	P1830 US	2140

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
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EXAMINER

MCEVOY, THOMAS M

ART UNIT	PAPER NUMBER
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4123

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/826,653	Applicant(s) BARONE, DAVID D.	
	Examiner THOMAS MCEVOY	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1) in view of Gilson et al. (US 6,336,934 B1) and in further view of Ouriel et al. (US 2003/0097094).

Greenhalgh discloses a tubular intraluminal filter, as best seen in Figure 1, comprising:

proximal and distal ends (40 and 38), a longitudinal axis (18), a collapsed configuration and an expanded configuration (Figures 2a and 2b); the expanded configuration having a generally cylindrical body and adjoining proximal and distal sections that taper from the cylindrical body to proximal and distal filter ends, respectively (Figure 2b: when expanded against a vessel wall, as is the intended expandable state, the filter body portion is generally cylindrical); wherein relative movement of the proximal and distal ends along the axis accompanies transformation of the filter between the collapsed

configuration and the expanded configuration (coaxial movement of the filter ends accompanies expansion and contraction in Figures 2a and 2b; opposite axial movement in combination with coaxial movement accompanies expansion and contraction in the Figure 5 embodiment); the filter comprising: a first array of braided filaments extending proximally from the filter distal end to a proximal terminus within a junction region between the cylindrical body and the tapered proximal section (30); and a second array of filaments inter-braided with the first array and extending a full length of the filter, wherein the filter proximal section is defined by two or more strands (32); wherein the filter proximal section has two or more inlet ports defined by open spaces between the two or more strands (42); wherein filter pores are formed by interstices between the braided filaments (34); wherein the proximal terminus of the first array is coupled to the second array by a retention member comprising joints formed where filaments of the first array overlap filaments of the second array wherein the joints are formed by one or more joining methods selected from adhesive bonding, heat bonding, melt bonding, soldering, brazing, welding, laser welding, resistance welding, and spot welding (column 6, lines 43-45); wherein the filter has a shape memory of the expanded configuration and has a shape memory of the collapsed configuration (see Abstract); a filter catheter comprising a flexible elongate shaft and a filter as described above mounted about a distal end of the shaft (20), and an actuation system for causing relative movement of the filter proximal and distal ends along the longitudinal axis of the filter which is connected to a flexible elongate shaft (figures 2a and 2b).

Greenhalgh does not disclose that the filaments of the second array are intra-braided to form two or more strands in the filter proximal section.

Attention is drawn to Gilson et al. who disclose a filter of similar structure to Greenhalgh as well as the claimed invention, as best seen in Figure 39, where the strands of the proximal section are bundled together into two or more strands which creates large inlet openings in the proximal section (column 6 - lines 45 to 47; Brief Description of Drawings). Further attention is drawn to Ouriel et al. who teach that the

strands of the proximal section may be bundled by intra-braiding 40 wires into 10-wire bundles, where the intra-braided bundles (or strands) extend the full length of the proximal section (paragraph 0067; Figure 13).

It would be obvious to one of ordinary skill in the art, having the teachings of Greenhalgh, Gilson et al. and Ouriel et al. before him or her, to intra-braid the filaments of the second array, in the proximal section, to form two or more strands where the intra-braided strands extend the full length of the proximal section, in order to create the larger inlet holes of the proximal section as taught by Gilson et al. and Ouriel et al.

4. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1) in view of Gilson et al. (US 6,336,934 B1) and in further view of Ouriel et al. (US 2003/0097094) as applied to claims 1-3 and 6-10 above, and further in view of Hyodoh et al. (US 2003/0040771).

The combination of Greenhalgh in view of Gilson et al. and in further view of Ouriel et al. teaches the invention discussed above but fails to teach a retention member comprising an elastic encapsulating sleeve.

Attention is directed to the Hyodoh et al. reference which discloses an intraluminal filter, as best seen in Figure 34, of similar structure as described above but further including an expandable (or elastic) encapsulating sleeve (710) which is joined to the filaments (paragraph 0230) to cover (or retain within) the majority of the body of the filter (as seen in Figure 34) in order to facilitate manipulation of the filter within a sheath.

Therefore, it would have been obvious to one having ordinary skill in the art and having the teachings of Greenhalgh, Gilson et al., Ouriel et al. and Hyodoh et al. before him or her to cover a majority or substantial portion of the filter with an expandable sleeve, in order to facilitate manipulation of the filter within a delivery sheath, where it would be obvious to cover any portion of the filter which could be more easily manipulated within the sheath by enclosure within a sleeve, while not substantially obstructing the inlet holes in the proximal section. This reasonably would include the

junction between the proximal and distal arrays. Furthermore, the coupling of the filaments between the arrays would be facilitated by the fixed attachment of the sleeve to the filaments of both arrays at the junction region.

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1), in view of Gilson et al. (US 6,336,934 B1), in further view of Ouriel et al. (US 2003/0097094) and further in view of Molgaard-Nielsen et al. (US 4,619,246).

Greenhalgh discloses a method for making the filter comprising: braiding multiple filaments to form a filter precursor tube (Figure 8, top two boxes); demarcating tube regions that are intended to become a proximal filter section, a cylindrical filter body, and a junction region there between; severing selected filaments at the junction and removing severed filaments from the proximal filter section (Figure 8, third and forth box from top; gathering the ends of a filter tube and removal of filaments from a proximal end implies a determination or demarcation of tube regions intended to become the proximal, cylindrical and junction regions as claimed).

Greenhalgh does not disclose dividing the un-severed filaments in the proximal filter section into two or more groups; intra-braiding each group of filaments into a corresponding strand; and heat-treating the filter to set a selected shape thereof.

Gilson et al. disclose a filter of similar structure to Greenhalgh as well as the claimed invention, as best seen in Figure 39, where the strands of the proximal section are bundled together into two or more strands (column 6 - lines 45 to 47; Brief Description of Drawings). Ouriel et al. teach that the strands of the proximal section may be bundled by intra-braiding 40 wires into 10-wire bundles and where the intra-braided bundles (or strands) extend the full length of the proximal section (paragraph 0067; Figure 13). Gilson et al. further disclose that the filter material could have shape memory to the expanded state (column 6, line 33) where heat treatment is a known technique in the art for obtaining shape memory characteristics for intraluminal filters as taught by Molgaard-Nielsen et al. (column 1, paragraph 3).

It would be obvious to one of ordinary skill in the art, having the teachings of Greenhalgh, Gilson et al., Ouriel et al. and Molgaard-Nielsen et al. before him or her, to bundle the filaments of the proximal section to form two or more strands as taught by Gilson et al. (to create larger inlet pores), where the strands can be bundled by intra-braiding and extend the full length of the filter proximal section as taught by Ouriel et al., and further heat treat the filter as taught by Molgaard-Nielsen et al. (to set a desired shape).

Response to Arguments

6. Applicant's arguments with respect to the grounds for the claim rejections have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant makes the additional argument that the level of skill was not resolved or articulated in the applied prior art. Examiner respectfully disagrees with this assertion and points out that the level of skill that was applied in the prior art of reference was (and is again) articulated as "one of ordinary skill in the art" by the examiner in the last paragraph for each 103(a) rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, this action is made final. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is 571-270-5034. The examiner can normally be reached on M-F, 7:30-5:00 (alternate Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

/Joseph S. Del Sole/

Supervisory Patent Examiner, Art Unit 4123